PRAIRIE PRESCRIPTIONS PILOT PROJECT

A Plan to Help Lower Prescription Drug Costs for North Dakotans

An Initiative by U.S. Senator Byron L. Dorgan

January 2004

PRAIRIE PRESCRIPTIONS PILOT PROJECT
EXECUTIVE SUMMARY

Senator Byron L. Dorgan is proposing to establish a two year pilot project in North Dakota, called the Prairie Prescriptions Pilot Project, to allow state-licensed pharmacists and drug wholesalers to purchase approved prescription drugs from licensed Canadian pharmacies and wholesalers. Such a pilot project has the potential to save North Dakota residents up to $81 million annually by allowing consumers to receive more affordable medications, with the added benefit of enabling them to continue using their local pharmacy.

Senator Dorgan is seeking the approval of the Secretary of Health and Human Services to permit this pilot project to go forward. Sections 1121 and 1122 of the Medicare Prescription Drug, Improvement, and Modernization Act authorize the HHS Secretary to allow for the importation of Food and Drug Administration (FDA)-approved medicines from Canada and further require the Secretary to conduct a study on drug importation. The Prairie Prescriptions Pilot Project will allow the Secretary to evaluate the safety and cost effectiveness of drug importation programs.

The Prairie Prescriptions Pilot Project is fundamentally different from the drug importation programs being implemented or considered in dozens of other states and cities across the United States. While all of the programs have the same goal of making prescription drugs more affordable for consumers, the North Dakota pilot project is unique in that it would use licensed pharmacists and drug wholesalers – who are experts in the handling and sale of prescription drugs -- to do the importing of approved medicines from Canada on behalf of their customers. The other states and cities that are developing drug importation programs would continue to rely on individual consumers to do their own importing.

Individual North Dakota consumers who wish to continue purchasing their medicines from Canada, under the FDA's "personal use" policy, would continue to be able to do so. However, while such "personal use" importation is certainly very helpful to individual consumers, it does not create the competitive pharmaceutical marketplace that will ultimately force the big pharmaceutical manufacturers to lower their prices in the United States.

Approval of the Prairie Prescriptions Pilot Project is necessary because prescription drug expenditures have been rising at an unsustainable rate. Consider the following:

- Prescription drug spending has been increasing by double digits for the last several years: by 15 percent in 2002; by 16 percent in 2001; by 16 percent in 2000; and by 16 percent in 1999.

- Moreover, pharmaceutical costs are projected to increase by 11 percent per year over the next decade.[1]

- Although an increase in pharmaceutical utilization contributes to this increase, the increase in the price of prescription drugs is also an important factor. Between 1993 and 2001, the average price of a prescription filled in the United States increased by 86 percent.[2]

This pricing pressure, which is largely responsible for driving up health insurance premiums, is forcing American consumers, state and local governments, businesses, and insurance plans to seek ways of reducing their prescription drug expenditures. Increasingly, these health care purchasers are turning to Canada as a source of quality, affordable prescription medicine.

In short, the Prairie Prescription Pilot Project would be a model for lowering prescription drug prices while still maintaining the safety of our drug supply.

PRAIRIE PRESCRIPTIONS PROJECT

North Dakotans filled 7.7 million prescriptions in 2002, at a total retail cost of nearly $396 million. This represents an increase in the total sales of retail prescriptions of 13 percent over the 2001 sales level.[3]

The Prairie Prescriptions Project, North Dakota's pilot program, would allow North Dakota's 614,000 residents to benefit from drug importation without putting the onus on individual consumers to do their drug purchasing in Canada. Under this two-year pilot project, North Dakota licensed pharmacists and drug wholesalers would be allowed to purchase Canadian medicines from licensed Canadian pharmacies and wholesalers and pass along the savings to their customers. The Prairie Prescriptions Program could save all North Dakota purchasers, including individual consumers, the state of North Dakota, local governments, employers, and health plans, as much as $81 million per year.[4]

North Dakota is especially well situated to conduct this pilot project for a number of reasons. For one, North Dakota has a smaller population, making it easier to track the safety and cost savings associated with drug importation. In addition, North Dakota's close proximity to Canada makes importation logistically easier, and in fact, many North Dakotans already purchase their prescription drugs from Canada, under the FDA's "personal use" enforcement discretion policy. Under this project, individual North Dakota consumers would no longer need to buy their medicines from Canada in order to get the lower prices available there.

North Dakota-licensed pharmacists and drug wholesalers would be eligible to import approved medicines purchased from licensed Canadian pharmacies or licensed Canadian drug wholesalers. Participating Canadian pharmacies and drug wholesalers would have to agree to be licensed in North Dakota and subject to inspection by North Dakota officials. Licensed North Dakota and Canadian pharmacies and drug wholesalers that wish to participate in the pilot project would be required to register with the North Dakota State Board of Pharmacy.[5] The

North Dakota Board of Pharmacy would further ensure that licensed North Dakota wholesalers that participate in the pilot project only sell imported medicines to North Dakota pharmacies.

Pharmacists and wholesalers importing approved medicines would be required to acquire and maintain documentation from the Canadian seller specifying: the name and quantity of the prescription drug imported; the original source of the prescription drug; and the lot or control number assigned to the prescription drug by its manufacturer.

Pharmacists and wholesalers would only be allowed to import approved medicines that are regulated under the Canadian drug regulatory system. The importation of controlled substances would not be allowed. To help facilitate importation and to ensure that only eligible prescription drugs are imported, the North Dakota State Board of Pharmacy would consult with the FDA and pharmacies and drug wholesalers to develop a list of the medicines that can be imported.

The North Dakota State Board of Pharmacy would also develop a web site that would include an adverse event reporting form, similar to the FDA's MedWatch reporting program. Consumers, pharmacists, and health care providers could report adverse health events associated with taking imported medication via this form. North Dakota would make this information available to the HHS Secretary for evaluation of the pilot project.

Finally, North Dakota participating pharmacies and drug wholesalers would only be permitted to re-sell imported approved medications as customary in their ordinary course of business. The State Board of Pharmacy would enforce this requirement. This limitation would allow North Dakota to be a test site for evaluating the safety and cost effectiveness of drug importation without creating a competitive disadvantage in the American pharmaceutical marketplace.

Allowing pharmacists to do the importing would enable North Dakota patients to stay at home and continue using their local pharmacy and would ensure that pharmacists could coordinate their customers' pharmaceutical care, thus providing added safety and protection for the public related to their use of Canadian drugs.

EVIDENCE OF COST SAVINGS

American consumers are currently paying the highest prices in the world for prescription drugs. A number of studies by the U.S. General Accounting Office, Congressional committees, and other entities have verified that the same prescription drugs cost, on average, 38 percent less in Canada than in the United States.[6] The savings is often even higher for brand-name pharmaceuticals that are heavily advertised in the U.S.

According to some estimates, as many as 10 million individual American consumers[7] imported as much as $500 million to $1 billion worth of medicines from Canada in 2002.[8] It seems unlikely that these consumers would make the effort to purchase their medicines from Canada if they were not saving money.

Following is a chart comparing the average retail prices of the top prescription drugs sold in North Dakota with the prices for the same drugs in Canada. As the chart demonstrates, every single drug costs significantly more in North Dakota. On average, the North Dakota prices were nearly double the Canadian prices. The Prairie Prescriptions Program could save North Dakota and its residents $81 million annually if this program were implemented.

Comparison of Prescription Drug Retail Prices
North Dakota vs. Canada

Prescription Drug (90 day supply)	Use	Average ND Retail Price	Average Canadian Retail Price	Percent Higher in ND
Lipitor 20 mg/tablet	Lower cholesterol	$315.01	$198.81	158%
Prevacid 30 mg/capsule	Anti-ulcerant	$425.88	$217.17	196%
Zocor 20 mg/tablet	Lower cholesterol	$413.19	$227.67	182%
Celebrex 200 mg/capsule	Arthritis	$244.85	$126.10	194%
Zoloft 50 mg/tablet	Depression	$242.77	$154.77	157%
Paxil 20 mg/tablet	Depression	$279.40	$162.95	172%
Zyprexa 20 mg/tablet	Depression	$1,761.18	$940.92	187%
Norvasc 5 mg/tablet	High blood pressure	$148.37	$115.74	128%
Nexium 40 mg/capsule	Acid reflux	$421.39	$250.11	169%

Average Percentage Higher In ND	171%

There have been some questions about whether the savings would actually be passed along to consumers under a system of drug importation and whether the savings would be eaten up through the administrative costs of importing drugs from Canada. The highly competitive

nature of the pharmacy marketplace will ensure that the savings are passed along. Community pharmacies generally have modest gross margins and low profits.[9] In addition, their customers who do not have insurance coverage for prescription drugs are extremely price sensitive and will take their business to mail-order companies or elsewhere if the lower prices are not passed on. As a result, pharmacists will have little choice but to pass the lower costs on to their customers.

A look at the experience within the European Union reaffirms that the savings from drug importation would be passed along to consumers. For more than 20 years now, there has existed a system of parallel prescription drug trade among the countries of the European Union – essentially the same thing being proposed between the United States and Canada. According to a study by health economists, the direct savings accruing to payers and patients in just five European countries – the United Kingdom, Germany, Sweden, Netherlands, and Denmark – as a result of parallel trade totaled $734 million in 2002.[10] This direct savings does not include the indirect downward pressure that parallel trading puts on drug prices, which further benefits all drug purchasers. By some estimates, parallel trading in prescription drugs saves the European Union $4.5 billion a year.[11]

ADDRESSING SAFETY CONCERNS

There should be no question that the prescription medicines purchased in Canada are at least as safe as those available in the United States. Indeed, according to a Canadian official, most of the pharmaceuticals marketed and distributed in Canada are made in the United States.[12] In fact, in 2000, the U.S. exported $2.2 billion in pharmaceuticals to Canada.

A comparison of the American and Canadian drug approval and distribution systems conducted by the non-partisan Congressional Research Service (CRS) has found that the U.S. and Canadian systems are similar in all respects.[13] For instance, both countries have similar requirements and processes for reviewing and approving pharmaceuticals, including compliance with good manufacturing practices (GMPs). The countries have similar rules governing the kinds of information that must be included in the labeling of medicines. The Canadian federal government inspects drug manufacturing facilities and drug wholesalers, and the provincial governments inspect Canadian pharmacies. Canadian pharmacists and drug wholesalers have to be licensed. Documentation of the "chain of custody" of prescription drugs is maintained in Canada. All prescription drugs sold in Canada are assigned a drug identification number that must be displayed on the package label. In addition, prescription drugs shipped in Canada must, by law, include the name and address of each company involved along the chain of distribution.

Other reviews of the Canadian drug regulatory system affirm its safety. For instance, both the states of Illinois and Minnesota have sent officials to Canada to meet with Canadian officials and to inspect its pharmacies and drug wholesalers. Both states have found that the Canadian system offers comparable protections to those available in the United States. In fact, Illinois found that the Canadian system is actually less vulnerable to drug counterfeiting than is the U.S. system.[14]

There has been some concern raised that medicines imported from Canada would somehow bypass the Canadian drug regulatory system. However, Health Canada officials,

Canada's equivalent of the FDA, recently clarified that *all* drugs sold in Canada, whether for Canadian consumption or for export to the United States, have to meet Canada's drug safety requirements. According to Daniele Dionne, Health Canada's associate director general, "As soon as any drug crosses the border into Canada, it has to meet all the regulations of our laws."[15]

The United States currently has a "closed" drug distribution system, in which prescription drugs flow from the drug manufacturer, to licensed drug wholesalers, to licensed pharmacists, and finally to consumers. Canada has a similarly closed system. This closed system would be maintained under the Prairie Prescriptions Program – prescription drugs would be purchased only by licensed U.S. pharmacists and wholesalers from licensed Canadian pharmacists or drug wholesalers that have purchased the FDA-approved medicines from the drug manufacturer.

In addition, despite the large number of Americans who are purchasing their medicines in Canada, there have been no reports of Americans being harmed by taking counterfeit or adulterated medicines from Canada.

The Prairie Prescriptions Program could also serve as a model for improving safety by giving the thousands of Americans who are going to continue trying to get their medicines elsewhere a safer, monitored alternative. The FDA has expressed concern about the large number of consumers who are resorting to getting their medicines via the Internet, with the associated risks of receiving expired, contaminated, or even counterfeit medicines that the FDA warns is a possibility from foreign outlets. The U.S. Customs Service estimates that more than 2 million packages of pharmaceuticals come by international mail to the United States per year.[16] The FDA admits that its system is "overwhelmed" by the large number of incoming mail-order packages containing pharmaceuticals.[17] The agency is able to inspect only 1 percent of pharmaceutical parcels entering the United States.[18] By setting up a closed, closely monitored system of drug importation, the FDA could focus its resources where problems are most likely.

It is also worth noting that the United States already imports billions worth of pharmaceuticals from all around the world – but only the big drug manufacturers are allowed to do this importing. For instance, the cholesterol-lowering drug Lipitor is manufactured in Ireland. Nexium, the "new purple pill" used for treating acid reflux and other stomach problems, is made in France. All told, the drug industry imported $14.7 billion in pharmaceuticals to the United States in 2001.[19]

Even the federal government shops for pharmaceuticals in the foreign market. American consumers and pharmacists should likewise be able to do so. When the Department of Defense needed additional doses of anthrax vaccine after its domestic supplies had run out, the Pentagon re-imported 23,000 doses of the vaccine from Canada.[20] Indeed, even U.S. Bureau of Customs officials, who are charged with enforcing the ban on imported drugs, are purchasing their medicines in Mexico and other foreign countries to take advantage of the lower prices.[21]

LEGAL CONSIDERATIONS

When Congress enacted Section 1121 of the Medicare Prescription Drug, Improvement, and Modernization Act (P.L. 108-173), it intended to design a system that would give desperate

American consumers an alternative to traveling to a foreign country or ordering their medicines via the Internet. Such a system would also allow Americans to continue seeing their own doctors and would also help to prevent dangerous drug interactions by allowing them to purchase all of their medicines from their local pharmacy, where their care could be coordinated. The Prairie Prescription Program serves as a model for the type of system envisioned under Section 1121.

Section 1121 of the new Medicare Prescription Drug, Improvement, and Modernization Act authorizes the Secretary of Health and Human Services to allow for the importation of Food and Drug Administration (FDA)-approved medicines from Canada by U.S.-licensed pharmacists and drug wholesalers for commercial re-sale. However, this Act requires the Secretary to first certify to the safety and cost effectiveness of drug importation before Section 1121 becomes effective.

In order to help the Secretary to make a determination on this certification for the entire country, North Dakota proposes a pilot project that would test the safety and cost effectiveness of importing prescription medicines from Canada by licensed North Dakota pharmacists and drug wholesalers. North Dakota requests that the Secretary grant the certification with respect to North Dakota to allow this demonstration project to go forward, using the Secretary's authority under Sections 1121 and 1122.

While the HHS Secretary has declined to make a similar certification with respect to a *different* law (the Medicine Equity and Drug Safety Act of 2000) that would have allowed commercial drug importation from 25 major industrialized nations, the Secretary has not been asked to make such a certification with respect to a Canada-only program. The well-documented savings available on prescription medicines sold in Canada, as well as the similarities of the Canadian drug safety system to our own, should make the Secretary's certification of a Canada-only program not only possible but irrefutable.

In addition, the HHS Secretary has the enforcement discretion to allow this pilot project to go forward, just as the FDA has utilized its enforcement discretion with respect to personal use importation.

ENDNOTES

[1] "Health Spending Projections for 2002-2012," Stephen Heffler, Sheila Smith, Sean Keehan, Greg Won, Kent Clemens and Mark Zezza, Centers for Medicare and Medicaid Services Office of the Actuary, *Health Affairs Journal*, January/February, 2004.
[2] Kaiser Family Foundation, "Prescription Drugs: Facts At a Glance."
[3] Kaiser Family Foundation State Health Facts Online.
[4] Testimony of Alan Sager, Ph.D., Boston University School of Public Health, September 5, 2001.
[5] The North Dakota State Board of Pharmacy already licenses pharmacies and drug wholesalers operating in North Dakota. In Canada, pharmacies are licensed at the provincial level and drug wholesalers are licensed at the federal level.
[6] "Prescription Drugs: Companies Typically Charge More in the United States than in Canada," U.S. General Accounting Office, September, 1992. "Prescription Drug Prices in Canada, Europe, and Japan," House Committee on Government Reform Minority Staff, April, 2001. "Affordable Medications for Americans," Alan Sager and Deborah Socolar, Boston University School of Public Health, July, 1999.
[7] "Millions of Americans Look Outside U.S. for Drugs," *Washington Post*, October 23, 2003.
[8] IMS data.
[9] 2003 NCPA-Pfizer Digest.
[10] P. West and J. Mahon, "Benefits to Payers and Patients from Parallel Trade," York Health Economics Consortium, May, 2003.
[11] "EU Court's Top Adviser Backs Drug Discounters," *Wall Street Journal*, September 11, 2003.
[12] , "Comparison of U.S. and Canadian Requirements for Approving and Distributing Prescription Drugs," Congressional Research Service Memorandum to Senator Byron L. Dorgan, September, 2001.
[13] Ibid.
[14] "Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs From Canadian Pharmacies," Illinois Department of Central Management Services, Office of Special Advocate for Prescription Drugs, October, 2003.
[15] "Canada to Guarantee Imported Medicine," *Washington Post*, May 8, 2003.
[16] "Millions of Americans Look Outside U.S. for Drugs," *Washington Post*, October 23, 2003.
[17] Testimony of John M. Taylor III, FDA Associate Commissioner for Regulatory Affairs, Hearing before the U.S. Senate Committee on Commerce, Science and Transportation, November 20, 2003
[18] FY2002 FDA Budget Submission to Congress.
[19] International Trade Commission data.
[20] "U.S. short of vaccine for deadly anthrax," *Toronto Star*, September 20, 2001.
[21] "Millions of Americans Look Outside U.S. for Drugs," *Washington Post*, October 23, 2003.